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**IN THE UNITED STATES DISTRICT COURT**

**FOR THE DISTRICT OF MINNESOTA**

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| **David H. MADDEN**, an individual<br>Plaintiff,<br><br>*v.*<br><br>**BREG, Inc.**, a California corporation, *and* **DOEs 1-10**,<br>Defendants | Case No.: .....<br><br>**PERSONAL INJURY; NEGLIGENCE; PRODUCTS LIABILITY**<br>(28 U.S.C. § 1332)<br><br>Related to: 08-CV-5035 *et al.*, actions consolidated before Judge John R. Tunheim and Magistrate Judge Jeffrey J. Keyes |

## Introduction

1. Plaintiff David MADDEN developed chondrolysis in his left shoulder following a routine arthroscopic surgery. The chondrolysis was caused by a "pain pump" manufactured by Defendants. (A pain pump is a device designed to administer anesthetic drugs into the joint after surgery to control pain.) Upon information and belief, the device was properly installed by the surgeon following the manufacturer's recommended usage, and the subsequent extended bathing in anesthetic of the joint

surfaces caused damage to the cartilage and its supporting cells. As a result, the plaintiff has suffered the complete or nearly complete loss of cartilage in the shoulder joint, an injury that is irreversible, disabling, and extremely painful. This lawsuit asserts claims for negligence, strict product liability for design defect, strict product liability for failure to warn and breach of implied warranty against the Defendants responsible for the design, manufacture, production, testing, study, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of the pain pump products that caused Mr. MADDEN's chondrolysis.

**Jurisdiction and Venue**

2. Venue is proper in this district under 28 U.S.C. §1391 because all defendants transact business in this district.

3. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332 because the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000^{00}$), exclusive of interest and costs, and because there is complete diversity of citizenship between the plaintiff and defendants.

**Plaintiff**

4. David MADDEN is a U.S. citizen and was a resident of California at the time of the surgery. He is presently a resident of Portland, Oregon.

5. Mr. Madden underwent the shoulder surgery at the Center for Orthopedic Surgery, Inc. in Van Nuys, California (near Los Angeles).

6. Upon information and belief, a catheter connected to a BREG Pain Care

3000 device designed, manufactured, and marketed by Defendant BREG was implanted into his left shoulder during the surgery on July 19, 2001. The device was loaded with 100cc of 0.5% Marcaine®, a local anesthetic, and epinephrine; which mixture was delivered through the catheter at a 2cc/hour rate over the next two days. The pain pump thus injected pain relief medication directly into the shoulder joint on a continuous basis for about two days following the surgery.

7. After recovery from the surgery and physical therapy, Plaintiff regained normal use of the shoulder for a short time, but subsequently experienced progressively decreased strength and range of motion. Eventually, these symptoms in conjunction with increasing pain impelled Plaintiff to seek medical attention, and he was diagnosed with chondrolysis of the left shoulder on or around February, 2011.

8. The incidents causing the injury, and from which Mr. MADDEN's claims arise, occurred on or shortly after the administration of anesthetics via post-operative pain pump following his surgery on July 19, 2001. Plaintiff first learned that the administration of pain medication from a pain pump directly into the shoulder joint could cause chondrolysis in approximately February, 2011.

**Defendants**

9. Defendant BREG, Inc. ("BREG") is a California corporation with its principal place of business in Vista, California. BREG manufactured, promoted and distributed the pain pump that was placed in plaintiff's shoulder. BREG conducted regular and sustained business in Minnesota by selling and distributing its products in Minnesota.

10. Upon information and belief, Defendants DOEs 1-10 ("DOEs") worked with BREG to design, develop, test, manufacture, market, recommend, sell and distribute the pain pump products, and are responsible in part for Plaintiff's injuries. The DOE defendants' identities are presently unknown to Plaintiff, but when they are discovered, Plaintiff will seek leave to amend this complaint to state their true names.

**Common Allegations**

11. At all relevant times, Defendants designed, manufactured, and distributed a product called a "pain pump," a medical device intended to deliver, via catheter, continuous doses of pain relief medication directly into the shoulder joint space. Pain pumps deliver anesthetic pain medication directly into the operative site for up to 72 hours or more following shoulder surgery.

12. Pain pumps are designed and intended to be used with commonly-used anesthetics such as Marcaine, with or without epinephrine, in volumes of up to 270 cc or more, over two days or more. The continuous injection of such medications at such doses over time directly into the shoulder joint, however, can cause serious and permanent damage to the cartilage of the shoulder joint. The plaintiff had a pain pump inserted post-operatively, and he received dangerous doses of continuously injected medication in his shoulder joint. As a result, he suffered narrowing of the joint space and a condition called "chondrolysis," which is the complete or nearly complete loss of cartilage in the shoulder joint. Chondrolysis is an irreversible, disabling, and extremely painful condition.

13. Plaintiff has suffered a significant narrowing of the joint space and

chondrolysis caused by the dangerously defective pain pumps. Mr. MADDEN will require a partial or total shoulder replacement soon, and is likely to require at least one more replacement in his lifetime due to the modest durability of the materials available for use in prosthetic joints. Shoulder replacement is a major, expensive and painful operation.

14. None of the defendants warned the Plaintiff or his surgeon about the unreasonable risks and dangers of using the pain pump and anesthetic medications in this manner. Plaintiff's surgeon used the pain pump in the manner instructed and directed by the Defendants.

**First Claim for Relief**

(Strict Products Liability: Design Defect, Failure to Warn)

15. Plaintiff repeats and realleges preceding paragraphs 1 through 14.

16. The pain pump device and the anesthetic medications used in it were unreasonably and dangerously defective beyond the extent contemplated by ordinary patients with ordinary knowledge regarding the device, in one or more of the following particulars:

(a) The labeling failed to instruct or warn the U.S. medical community that the safety of the device and its medications had not been established for use in the shoulder joint space;

(b) The labeling failed to disclose to the U.S. medical community that continuous injection of commonly used anesthetics such as Marcaine (bupivacaine), with or without epinephrine, in volumes of up to 250 cc's,

for two or more days, into the shoulder joint space, may cause serious and permanent injury to the joint cartilage;

(c) The labeling failed to include a precaution against placing the catheter of the pain pump in the shoulder joint space;

(d) The labeling failed to provide to the U.S. medical community adequate instructions for the safe use of the device, failing specifically to identify anesthetic medications that could be safely and effectively used in the shoulder joint space;

(e) The labeling failed to disclose to the U.S. medical community that the effectiveness of the device was uncertain for use in the shoulder joint space;

(f) The labeling failed to disclose to the U.S. medical community that the FDA had considered the defendants' request to put this indication in the pain pump label, and then had rejected this precise indication for the pain pumps' use, to deliver the pain medicine directly into the joint space.

(g) The products were designed to inject commonly-used medications associated with damage to articular cartilage directly into the shoulder joint; and

(h) When used as designed, the pain pumps delivered, over time, dangerously high doses of medication directly into shoulder tissue.

17. The product defects alleged above were substantial contributing causes of the injuries suffered by the Plaintiff. Specifically, the pain pump and the anesthetic medication used in it caused Plaintiff to suffer the permanent loss of cartilage in his

shoulder, resulting in severe pain and discomfort of the shoulder and loss of use and function of the shoulder and arm, which will necessitate multiple follow-on surgeries. The use of a pain pump and the anesthetic medication used in it also rendered the therapeutic benefits of the shoulder surgery worthless. David MADDEN will require future medical care as he ages, which is likely to include future shoulder replacements. In addition, he has suffered mental distress and anguish and has suffered permanent impairment of the use and function of his affected upper extremity.

**Second Claim for Relief**

(Negligence)

18. Plaintiff repeats and realleges realleges preceding paragraphs 1 through 17.

19. At all relevant times, each of the Defendants knew or reasonably should have known that their pain pumps and the anesthetic medication used in them were unreasonably dangerous and defective when used as directed and as designed. A reasonably careful search and review of the scientific and medical literature, and other information, should have indicated to the Defendants that:

(a) Commonly used anesthetics likely to be used in their pain pumps, such as Marcaine, with or without epinephrine, were harmful to human and animal articular cartilage;

(b) Use of the pain pumps in a joint space had not been approved by the F.D.A., and in fact had been specifically rejected by the F.D.A.;

(c) Continuous injection of up to 250 cc's or more of such medications,

through a catheter, directly into the shoulder joint, for two days or more, had not been adequately tested for safety or effectiveness;

(d) The risk of chondrolysis and other serious post-operative problems associated with using the pain pumps and their medications as designed and instructed outweighed the possible benefits of such use.

20. Based on what they knew or reasonably should have known as described above, the Defendants were each negligent in one or more of the following particulars:

(a) In failing to instruct or warn the U.S. medical community that the safety of the device had not been established for use in the shoulder joint space;

(b) In failing to disclose to the U.S. medical community that continuous injection of commonly-used anesthetics such as bupivacaine, with or without epinephrine, in volumes of up to 250 cc's, for two or more days, into the shoulder joint space, may cause serious and permanent injury to the joint cartilage;

(c) In failing to include a precaution against placing the catheter of the pain pump in the shoulder joint space;

(d) In failing to provide to the U.S. medical community adequate instructions for the safe use of the device, specifically failing to identify anesthetic medications that could be safely and effectively used in the shoulder joint space;

(e) In failing to disclose to the U.S. medical community that the effectiveness of the device with these medications was uncertain for use in the shoulder joint space;

(f) Manufacturing a product designed to directly inject into the shoulder joint commonly used medications associated with damage to articular cartilage;

(g) Manufacturing a product designed to deliver, over time, dangerously high doses of medication directly into shoulder tissue;

(h) Failing to conduct studies or otherwise investigate the potential harm to articular cartilage when exposed to the pain pumps and anesthetic medications in volumes of at least 250 cc's, for two or more days, into the shoulder joint space; and

(i) Promoting the pain pumps for use in the joint space after the FDA had considered and rejected such an indication.

21. The negligent acts and omissions alleged above were substantial contributing causes of the injuries suffered by Mr. MADDEN. Specifically, the pain pump caused David MADDEN to suffer the permanent loss of cartilage in his shoulder, resulting in severe pain and discomfort of the shoulder, and loss of use and function of his shoulder and arm. The use of the pain pump also rendered the therapeutic benefits of his shoulder surgery worthless. As a result of the Defendants' negligent acts and omissions, David MADDEN will incur additional medical expenses as he ages. In addition, he has suffered mental distress and anguish and has suffered permanent impairment of the use and function of his affected upper extremity.

22. The injuries suffered by Plaintiff were the reasonably foreseeable results of Defendants' negligence.

**Prayer for Relief**

23. Wherefore, Plaintiff demands judgment against Defendants and each of them as follows:

(a) Plaintiff David MADDEN prays for judgment against each defendant for economic and noneconomic damages exceeding $75,000 in amounts to be proven at trial;

(b) Plaintiff seeks his reasonable costs and disbursements incurred herein, including the attorney fees he may incur in prosecuting this action;

(c) Plaintiff prays for such other and further relief as justice requires.

**Jury Demand**

24. Plaintiff requests trial by jury.

Digitally signed by David Madden
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Date

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